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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,156	11/15/2001	Avi J. Ashkenazi	P2730P1C28	5501

35489 7590 05/10/2004

HELLER EHRMAN WHITE & MCAULIFFE LLP  
275 MIDDLEFIELD ROAD  
MENLO PARK, CO 94025-3506

EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 05/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/998,156

**Applicant(s)**

ASHKENAZI ET AL.

**Examiner**

Robert Landsman

**Art Unit**

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 119-124 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 119-124 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/24/02</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Sequence Comparison</u> .             |

## **DETAILED ACTION**

### ***1. Formal Matters***

- A. The Preliminary Amendment dated 11/15/01, has been entered into the record.
- B. The Preliminary Amendment dated 9/3/02, has been entered into the record.
- C. Claims 119-124 are pending and are the subject of this Office Action.

### ***2. Priority***

Due to the excessive number of applications from which the present application claims benefit, priority cannot be determined. However, the Examiner has concluded that the subject matter defined in this application is not supported by any of the applications in the chain of priority because the presently claimed subject matter is not supported by a specific, substantial or well-established utility, nor, for this reason, is it enabled. Accordingly, the subject matter defined in claims 119-124 has an effective filing date of 11/15/01, which is the filing date of the present application.

Should the applicant disagree with the examiner's factual determination above, it is incumbent upon the applicant to provide the serial number and specific page number(s) of any parent application filed prior to 11/15/01 which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession of and fully enabled for prior to 11/15/01.

### ***3. Information Disclosure Statement***

- A. References 1 and 2 on the IDS dated 5/24/02 have been lined through since they are not in proper format, including author and accession number.

### ***4. Specification***

- A. Though none could be found, due to the length of the specification, Applicants are reminded that embedded hyperlink and/or other form of browser-executable code are not permitted in the specification. See MPEP § 608.01.
- B. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title recites polypeptides and polynucleotides whereas the claims are drawn to antibodies.

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C. The status of application 09/380,127 should be updated to “now abandoned” in the first line of the specification.

### **5. Claim Objections**

A. The syntax of claims 119-124 could be improved by replacing the phrase “shown in Figure 240 (SEQ ID NO:345)” in claims 119 and 124 with “of SEQ ID NO:345.”

### **6. Claim Rejections - 35 USC § 112, second paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claim 122 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not understood how an antibody can be both an “antibody” and a “fragment.” The phrase “an antibody, or fragment thereof,” for example, could be used in independent claim 119 and claim 122 could be cancelled.

B. Claim 124 is confusing since it is not clear what the definition of “specifically binds” is. This term is not defined in the specification. Furthermore, it is not clear how this claim differs from that of claim 119, where the antibody “binds” the protein of SEQ ID NO:345.

### **7. Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

A. Claims 119 and 124 are rejected under 35 U.S.C. 102(e) as being anticipated by Ni et al. (U.S. Patent No. 6,566,478). The claims recite an antibody which binds the protein of SEQ ID NO:345. Ni et al.

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teach a protein which is 66.5% identical to SEQ ID NO:345 of the present invention (Sequence Comparison). Ni also teach antibodies (Example 12).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

A. Claims 119-124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ni et al. in view of Goldenberg. The teachings of Goldenberg are recited in the above rejection under 35 USC 102. Ni do not teach monoclonal, humanized and labeled as well as fragments thereof peptides. However, Goldenberg et al. do teach the use of monoclonal, humanized and labeled antibodies (at least the Abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the present invention to have produced labeled monoclonal and/or humanized antibodies to the protein of the present invention for the purpose of producing cell-specific targeting of antibodies to treat human disease. One of ordinary skill in the art would have been motivated to produce these antibodies for the protein of the present invention in view of the teachings of Goldenberg (see entire document, especially "Conclusions and Hopes").

***10. Conclusion***

A. No claim is allowable.

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***Advisory information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.  
Patent Examiner  
Group 1600  
May 05, 2004

  
**ROBERT LANDSMAN**  
**PATENT EXAMINER**

# Sequence Comparison

```
; Patent No. 6566498
; GENERAL INFORMATION:
; APPLICANT: Ni, et al.
; TITLE OF INVENTION: Human Serine Protease and Serpin Polypeptides
; FILE REFERENCE: PF391
; CURRENT APPLICATION NUMBER: US/09/244,111
; CURRENT FILING DATE: 1999-02-04
; EARLIER APPLICATION NUMBER: 60/073,961
; EARLIER FILING DATE: 1998-02-06
; NUMBER OF SEQ ID NOS: 13
; SOFTWARE: PatentIn Ver. 2.0
; SEQ ID NO 12
; LENGTH: 76
; TYPE: PRT
; ORGANISM: Homo sapiens
US-09-244-111-12
```

```
Query Match          66.5%; Score 409; DB 4; Length 76;
Best Local Similarity 100.0%; Pred. No. 1.8e-38;
Matches 75; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
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Qy      1 MGSSSFVLVLMVSLVLTLLVAVEGVKEGIEKAGVCPADNVRCFKSDPPQCHTDQDCLGERK 60
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      1 MGSSSFVLVLMVSLVLTLLVAVEGVKEGIEKAGVCPADNVRCFKSDPPQCHTDQDCLGERK 60

Qy      61 CCYLHCGFKCVIPVK 75
          ||||||||||||||||
Db      61 CCYLHCGFKCVIPVK 75
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